

Claims 1-8 have been rejected under 35 U.S.C. §103(a) over Cook (U.S. Pat. No. 5,554,646) and Cook (U.S. Pat. No. 5,428,072) in view of Chin *et al.* Applicants believe that the present amendments and the following remarks traverse the Examiner's rejection of the claims.

REMARKS

The claims remain rejected under 35 U.S.C. §103(a) over Cook (U.S. Pat. No. 5,554,646) and Cook (U.S. Pat. No. 5,428,072) in view of Chin *et al.* Applicants believe the claims are in condition for allowance for the following reasons.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143). Failure to establish **any one** of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue.³ The Examiner has failed to provide references that teach each element of the claims and has failed to provide references that provide a reasonable expectation of success.

As previously described, the Examiner has failed to reply to Applicants' extensive arguments that the cited references do not teach each element of the claims. Instead of responding to these arguments, the Examiner states that "[n]ote, question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must [sic] considered. *In re Lamberti and Konert* (CCPA), 192 USPQ 278)."⁴ Applicants respectfully submit that this statement made by the courts cannot be taken out of context. The cited case involved claims to asymmetric dialkyl

³ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

⁴ Office Action, page 3.

moieties. The prior art did not expressly disclose these compounds, but did suggest such compounds by referencing at least one methylene group attached to the sulfur atom. This set of facts is completely different from the present case where it is being argued that the cited references do not teach how to make the compositions of the present invention and thus cannot provide each element of the claims.

The Examiner attempts to argue that "applicants conclusion that Cook would produce large amount of unwanted isomers is not convincing because the conclusion is based on result from a similar method, not from the method of Cook."⁵ In the Advisory Action, the Examiner further states that "The prima facie case have been established as set forth in the prior office action particularly because the difference between the prior art and claimed invention only involve impurity. Note applicants have the burden of showing that the prior art products do not necessarily or inherently possess the characteristics of his claimed products. Further, applicants have the burden of showing unexpected benefits of the claimed products."

Applicants believe that their previous arguments completely respond to and rebut these statements by the Examiner. Nevertheless, Applicants herein provide the Declaration of inventor Asgeir Sæbo. In the Declaration, Dr. Sæbo states that the methods of Cook would have necessarily produced a composition comprising greater than 2% 8,10 and 11,13 isomers of conjugated linoleic acid. Thus, Applicants have provided evidence that the prior art products do not necessarily or inherently contain less than 2% 8,10 and 11,13 isomers.

Furthermore, the Examiner's attention is also directed to the review article attached to Dr. Sæbo's Declaration. This article, Pariza, M.W., Y. Park, and M. E. Cook, "The biologically active isomers of conjugated linoleic acid," Progress in Lipids Research 40:283-298 (2001), is authored by the inventors of the cited prior art. At page 287, in section 2.2, they state:

For example, CLA that we typically produce for experimental purposes consists of the *cis*-9,*trans*-11 (40.8-41.1%), *trans*-10,*cis*-12 (43.5-44.9%), and *trans*-9,-*trans*-11/*trans*-10-*trans*-12 (4.6-10%) isomers.

⁵ Office Action, page 3.

This provides evidence that the CLA compositions of Cook and Pariza contained greater than the claimed less than 2% trans,trans; 8,10; and 11,13 isomers.

With respect to reasonable expectation of success, the Examiner states that "[t]he issue is: will a person with ordinary skill in the art be able to make such a composition, the issue is not whether Cook's disclosed method therein can make the claimed composition (in large scale)."⁶ The Examiner further states that making the claimed compositions is within the skill of the artisan. However, this contention is directly rebutted by Dr. Sæbo's Declaration.

Furthermore, Applicants respectfully submit that Examiner has misstated the standard for expectation of success. Reasonable expectation of success occurs when "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."⁷ Accordingly, contrary to the Examiner's assertion, the prior art (*i.e.*, the references cited by the Examiner) must provide a reasonable expectation of success in producing the claimed compositions. Reasonable expectation of success is determined in the context of what is disclosed in the cited references. Since the cited references do not disclose a method suitable for making the claimed compositions, there can be no reasonable expectation of success. Therefore, Applicants respectfully submit that the Examiner's summary of the issue is not in accordance with patent law standards. Accordingly, the Examiner has not established a *prima facie* case of obviousness and the Claims should be passed to allowance.

Conclusion

All grounds of rejection and objection of the Office Action of April 30, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

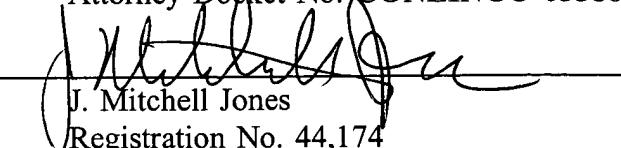
⁶ Office Action, page 3.

⁷ *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

PATENT

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APPENDIX I
MARKED-UP VERSION OF REWRITTEN, ADDED,
AND/OR CANCELLED CLAIMS

The following is a version of the claims pursuant to 37 C.F.R. §1.121 (c)(1)(ii) with markings showing changes made herein to the previous version of record of the claims.

IN THE CLAIMS:

Please amend the Claims as follows:

1. (Amended twice) A[n animal feed] food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.
2. (Amended once) The [animal feed] food product of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said [feed] food product is about 0.05 to 3.5 percent by weight.
3. (Amended twice) The [animal feed] food product of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecadienoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecadienoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester[, with less than [5] about two percent of 11,13-octadecanoic acid alkyl ester].

APPENDIX II

**CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS AS
AMENDED IN THIS COMMUNICATION**

1. (Amended twice) A food product comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent trans,trans; 8,10 and 11,13 octadecadienoic acid isomers.
2. (Amended once) The food product of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said food product is about 0.05 to 3.5 percent by weight.
3. (Amended twice) The food product of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecadienoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecadienoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester.
4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising
 - a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and
 - in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and
 - in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.
5. The ester of claim 4 wherein said c9,t11-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

6. The ester of claim 4 wherein said t10,c12-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

7. (Amended once) A conjugated linoleic acid alkyl ester composition for use in domestic animal feed, food ingredients, or human dietary supplements made by the process comprising

providing an unrefined linoleic acid alkyl ester having phosphatidyl residue in the range of about 0.1 to about 0.5 percent

treating with an alkali alcoholate at low temperature in the presence of a monohydric low molecular weight alcohol to cause isomerization of at least 50 percent of the linoleic acid alkyl ester to conjugated linoleic alkyl ester at low temperature,

acidifying by addition of an aqueous acid, and

separating the linoleic conjugated linoleic acid alkyl ester from said aqueous acid without distillation.

8. The ester of claims 1-7 wherein said alkyl ester has an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.